IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KILEY WOLFE, Plaintiff, v. MCNEIL-PPC, INC.; *et al.*, Defendants.	CIVIL ACTION NO.: 07-0348 Judge: Jan E. DuBois

1. PARTIES' JOINT STATEMENT OF THE CASE

Plaintiff Kiley Wolfe's claims are based on strict liability and negligent failure to warn. Plaintiff contends that in 1996 defendants were selling Children's Motrin over-the-counter with an inadequate warning label that failed to warn the consumer of the potential for allergic reactions to the drug and to "stop use" and see a doctor right away if any redness, rash or blisters occur.

Plaintiff contends that in 1996 she suffered a life-threatening allergic reaction to Children's Motrin that resulted in two medical conditions known as Stevens-Johnson Syndrome ("SJS") and Vanishing Bile Duct Syndrome ("VBDS") which required her to undergo a liver transplant and suffer other permanent injuries. Plaintiff further claims that defendants are liable to her for punitive damages. Plaintiff bases her claim on certain acts she contends defendants engaged in, including their withholding from the FDA two cases of SJS that appeared in the Boston University Fever Study, which formed the basis of defendants' application to the FDA for over-the-counter status of Children's Motrin.

Defendants respond that Kiley Wolfe's conditions were not caused by Children's Motrin or any conduct of defendants. Defendants further respond that the Children's Motrin label gave adequate warnings, and that a different warning would not have changed Kiley Wolfe's use of Children's Motrin. Defendants deny that they acted with any malice towards plaintiff and deny any other wrongdoing including they withheld any information from the FDA.

2. PLAINTIFF'S STATEMENT

Johnson & Johnson and McNeil's Children's Motrin caused plaintiff to suffer an allergic reaction

resulting in SJS and VBDS and resulting liver transplant and other permanent injuries. The defendants concealed from the FDA two instances of SJS from a large safety study conducted to obtain over-the-counter approval of Children's Motrin. The defendants obtained the FDA approval by hiding this information and one of the results was an inadequate warning label.

In May 1996, plaintiff had ordinary flu symptoms. Her mother took her to the doctor who diagnosed the flu and he recommended over-the-counter Children's Motrin. Plaintiff suffered an allergic reaction to the Children's Motrin and was later taken to Boston Children's Hospital. After one-and-a-half years of treatment, she was forced to undergo a liver transplant. Her treating physicians concurred that plaintiff suffered an allergic reaction to the Children's Motrin that resulted in SJS and VBDS, which necessitated the liver transplant and caused other injuries. Subsequently, plaintiff's case was published in a peer-reviewed journal article in Gastroenterology by three of her physicians to warn the medical community that ibuprofen products such as Children's Motrin cause such life threatening diseases as SJS and VBDS.

In 2006, as the result of a Citizen's Petition to the FDA about incidents of SJS caused by taking ibuprofen products such as Children's Motrin, the FDA recommended that warnings for over-the-counter ibuprofen products including Children's Motrin, be changed and strengthened and include reference to skin reddening, rashes and blisters - allergic reactions associated with SJS and warn customers that "if an allergic reaction occurs, stop use and seek medical help right away." These defendants agreed. Had the warning label in 1996 contained the language recommended by the FDA in 2006 or other similar language to "stop use", plaintiff's mother would have stopped giving plaintiff Children's Motrin and she would not have contracted SJS and VBDS and, therefore, would not have required a liver transplant nor suffered other permanent damages.

As a result of the SJS, VBDS and her liver transplant, Plaintiff has sustained permanent medical conditions for which she has received constant medical supervision, treatment and surgical procedures. Plaintiff is seeking both compensatory and punitive damages.

Plaintiff's Causes of Action

Plaintiff is asserting both strict liability failure to warn and negligent failure to warn claims

against all defendants. To succeed on her strict liability failure to warn claim, plaintiff must prove (1) that the product was defective, (2) that the defect existed when it left the hands of the defendant, and (3) that the defect caused harm. "A product is defective due to a failure-to-warn where the product was distributed without sufficient warnings to notify the ultimate user of the dangers inherent in the product."

On plaintiff's negligent failure to warn claim, plaintiff must prove that defendants (a) knew or had reason to know that the over-the-counter Children's Motrin was or was likely to be dangerous to the user for which it was supplied, and (b) had no reason to believe that those for whose use the Children's Motrin was supplied would realize its dangerous condition, and (c) failed to exercise reasonable care to inform users of its dangerous condition or of the facts which make it likely to be dangerous.

Plaintiff will prove that over-the-counter Children's Motrin was defective in 1996 due to a failure to warn because Children's Motrin was distributed without sufficient warnings to notify the ultimate users of the dangers inherent in the product and what to watch for regarding an allergic reaction, and warn to stop use and see a doctor right away.

Accordingly, Plaintiff contends that the defendants are liable to her for both compensatory as well as punitive damages. Plaintiff's claims for punitive damages are based on defendants implied malice. Implied malice exists where "deliberate conduct by the defendant, although motivated by something other than ill will toward any particular party, is so outrageous that malice toward a person injured as a result of that conduct can be implied."

Plaintiff denies that she or her mother is in any way negligent in causing plaintiff's injuries. With regard to defendant's contention that plaintiff was comparatively negligent in causing her injuries, plaintiff contends that as a matter of law, she cannot be found negligent because she was 9 years old at the time she took Children's Motrin. Any negligence on the part of anyone else is not imputable to the plaintiff. Finally, comparative negligence is not a defense to a strict liability claim.

3. DEFENDANTS' STATEMENT OF DEFENSES

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. is the party responsible for manufacturing and selling Children's Motrin. Plaintiff cannot prove Children's Motrin caused her

damages. Plaintiff cannot prove her failure to warn claims. First, she cannot prove Children's Motrin can cause SJS and VBDS. Second, she cannot prove that Children's Motrin caused her SJS and VBDS. Third, she cannot prove that a different warning would have prevented her damages because she cannot prove that a different warning would have made a difference in her mother giving her OTC Children's Motrin in May and June 1996. The evidence will show that, among other things, (1) Plaintiff's mother read only the dosing information – not the warnings – when first giving Children's Motrin to Plaintiff; (2) she continued administering Children's Motrin to Plaintiff upon her doctor's advice, after she allegedly studied the box and bottle that warned of the seriousness of the very symptoms Plaintiff was experiencing; (3) she had previously given Aleve to Plaintiff without reading the warning label on the product; (4) she gave Children's Motrin to her young sons even after Plaintiff's alleged reaction; and (5) she personally continues to use ibuprofen. A different warning on the Children's Motrin would not have made a difference in Plaintiff's use of the medicine.

Plaintiff cannot prove she is entitled to punitive damages. Plaintiff must prove by clear and convincing evidence that Defendants acted with malice in providing the allegedly inadequate warning. Malice exists only where a defendant's conduct is motivated by ill will toward the plaintiff or where deliberate conduct by the defendant is so outrageous that it shows malice toward the plaintiff. Plaintiff cannot prove either of these elements by clear and convincing evidence. There is no evidence that Defendants' conduct toward Plaintiff was either malicious or outrageous. Defendants sold Children's Motrin with an FDA-approved warning. As to risks of SJS, (1) the reliable scientific evidence indicates Children's Motrin does not cause SJS or VBDS; (2) McNeil submitted accurate information to the FDA regarding risks of SJS, and (3) after thorough review of the risks of SJS, the FDA determined that Children's Motrin was safe for OTC use and that OTC ibuprofen labels should not include an SJS warning. If, by a preponderance of the evidence, the jury finds plaintiff's negligence was a legal cause of any damage she experienced, it must apportion the relative degree of fault, and if greater than 50%, plaintiff is entitled to no damages.

CERTIFICATE OF SERVICE

I, Kadene K. Chin, hereby certify that on this day I caused a true and correct copy of the foregoing to be served via the Court's electronic filing system upon counsel listed below:

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Dated: August 22, 2011

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